

UTILITY PATENT APPLICATION

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Title: Radially Ported Needle for Delivering Bone Graft Material and
Method of Use

Related Applications

This application claims priority to U.S. Provisional Patent Application
Serial Number 60/415,503, filed October 3, 2003.

This application is related to Assignee's co-pending U.S Patent Application [720.112.2], filed the same day as this patent application.

BACKGROUND OF THE INVENTION

Field of the Invention

The present invention generally pertains to the use of graft materials for promoting bone growth and, more particularly, to ported needles for delivering bone graft materials to metaphyseal compression fractures, other bone voids or other bone defect areas.

Discussion of the Prior Art

In the past, bone graft materials have been delivered to bone defect areas, such as metaphyseal compression fractures or bone voids as well as other areas of bone structures having discontinuities, cavities, recesses or the like (hereinafter referred to as bone defect areas). Minimally invasive bone graft procedures are preferred in many cases, and the delivery or injection of bone graft material to the bone defect areas has been accomplished using a needle having an open distal end forming an axial port for delivering the bone graft material to the bone defect areas from a syringe coupled with the proximal end of the needle. Since the only opening for delivery of the bone graft material is the

1 axial port, the prior art needle has the disadvantages of: (1) being unable to
2 deliver bone graft material when the axial port abuts bone or other tissue, (2) not
3 being able to radially inject bone graft material, and (3) requiring undesirable
4 excessive force to eject bone graft material through the axial port.

5 SUMMARY OF THE INVENTION

6 Accordingly, it is an object of the present invention to overcome the above
7 mentioned disadvantages of the prior art by providing a radially ported bone graft
8 needle particularly useful in minimally invasive procedures. Another object of the
9 present invention is to deliver bone graft material to a bone defect area by
10 extruding the bone graft material both axially and radially simultaneously.

11 A further object of the present invention is to fill a bone defect area by
12 radial, multiaxial and/or multidirectional delivery of bone graft material. The
13 present invention is generally characterized in a bone graft needle having at least
14 one radial opening or port for delivering bone graft material radially to a bone
15 defect area.

16 The needle preferably has an axial opening or port allowing simultaneous
17 axial and radial delivery of bone graft material. Preferably, equally spaced radial
18 ports are arranged around the axial port; however, the size, arrangement and
19 configuration of the radial ports can be varied dependent upon particular
20 situations.

21 The present invention is further generally characterized in a method of
22 delivering bone graft material to a bone defect area including the steps of placing

1 the distal end of an elongate tubular delivery member of a bone graft needle
2 adjacent the bone defect area and flowing the bone graft material through the
3 delivery member to exit both radially and axially of the delivery member.

4 Some of the advantages of the present invention over the prior art are that
5 both axial and radial delivery of bone graft material at a bone defect area can be
6 achieved, radial delivery of bone graft material at a bone defect area can be
7 achieved producing a more even distribution of bone graft material, bone graft
8 material can be delivered even when the axial distal end opening of the needle is
9 blocked, and reduced pressure is required to deliver bone graft material to a
10 bone defect area.

11 BRIEF DESCRIPTION OF THE DRAWINGS

12 Fig. 1 is a perspective view of an instrument assembly incorporating a
13 bone graft needle according to the present invention.

14 Fig. 2 is an exploded side view of the instrument assembly including a
15 side view of the bone graft needle of the present invention.

16 Fig. 3 is a sectional view of a delivery member of the bone graft needle
17 taken along line A-A of Fig. 2.

18 Fig. 4 is an exploded side view of an alternative instrument assembly
19 incorporating an alternative bone graft needle according to the present invention.

20 Fig. 5 is a sectional view of the delivery member of the alternative bone
21 graft needle taken along lines B-B of Fig. 4.

1 Fig. 6 is a side view of another alternative bone graft needle according to
2 the present invention.

3 Fig. 7 is a side view of a further alternative bone graft needle according to
4 the present invention.

5 Other objects and advantages of the present invention will become
6 apparent from the following description of the preferred embodiments taken in
7 conjunction with the accompanying drawings, wherein like parts in each of the
8 several figures are identified by the same reference characters.

9 DESCRIPTION OF THE PREFERRED EMBODIMENTS

10 The present invention relates to a bone graft needle used to deliver bone graft
11 material to a bone defect area in a patient's body in a minimally invasive
12 procedure in which the bone defect area is accessed via a minimal portal or
13 incision. Figs. 1 and 2 illustrate an instrument assembly 10 comprising a bone
14 graft needle 12 and a penetrating member 14, such as a trocar. The bone graft
15 needle 12 comprises an elongate tubular delivery member 16 extending distally
16 from a handle 18. The delivery member 16 has an open distal end 20
17 communicating with a longitudinal passage 22 extending entirely through the
18 delivery member 16 and the handle 18. A hollow coupling 24 having open distal
19 and proximal ends is disposed at a proximal end of passage 22 with the interior
20 of the coupling 24 in communication with the passage 22. The coupling 24 is
21 designed for releasable attachment to a standard syringe and may be designed
22 as a conventional luer lock coupling. The handle 18 can have various

1 configurations to facilitate grasping. A proximal end of the delivery member 16
2 can be attached to the handle 18 via a hub 26 or in any desired manner. The
3 proximal end of the delivery member 16 can extend any desired distance into a
4 passage of the handle 18 or can extend entirely through the handle. The coupling
5 24 can be attached to the handle 18 in various ways or may be formed integrally,
6 unitarily with the handle. The distal end of the coupling 24 can extend any
7 desired amount into the passage of the handle 18. Accordingly, it should be
8 appreciated that the longitudinal passage 22 can be formed in its entirety by the
9 lumen of delivery member 16, can be formed in part by the lumen of the delivery
10 member 16 and by a passage in handle 18, or can be formed in part by the
11 lumen of delivery member 16, a passage in the handle 18 and the interior of the
12 coupling 24.

13 The delivery member 16, as best shown in Figs. 2 and 3, has an external
14 cross sectional diameter or size for insertion through a minimally invasive portal
15 or incision formed in the patient's body to access a bone defect area. The
16 delivery member 16 has an internal cross-sectional diameter or size to receive
17 the penetrating member 14 therethrough. As shown in Figs. 1 and 2, the
18 penetrating member 14 includes an elongate shaft 28 having a tissue penetrating
19 distal end 30 and having a proximal end attached to a hub 32. The shaft 28 is
20 insertable in the passage 22 extending entirely through the bone graft needle
21 and, when the hub 32 is in abutment with the handle 18, the tissue penetrating
22 distal end 30 protrudes distally from the open distal end 20 of the delivery
23 member 16 as shown in Fig. 1. The instrument assembly 10 formed when the

1 penetrating member 14 is inserted in the delivery member 16 can be utilized to
2 form a minimally invasive portal in anatomical tissue of a patient to establish
3 access to a bone defect area. The exposed tissue penetrating distal end 30 of
4 the penetrating member is used to penetrate the anatomical tissue to introduce
5 the distal end 20 of delivery member 16 at or near the bone defect area.
6 Thereafter, the penetrating member 14 can be removed from the bone graft
7 needle 12 leaving the bone graft needle in place to maintain the thusly formed
8 portal with the handle 18 disposed externally of the patient's body. It should be
9 appreciated, however, that the bone graft needle 12 can be used independently
10 of a penetrating member and that the bone graft needle can be introduced at or
11 near a bone defect area via a pre-established portal.

12 The open distal end 20 of delivery member 16 is circumscribed by a
13 circumferential edge 34 that is provided with one or more proximally curving
14 indentations as best shown in Fig. 2. Accordingly, the circumferential edge 34
15 comprises one or more distal most edge segments or points and one or more
16 proximal most edge segments or points spaced proximally from the one or more
17 distal most edge segments or points. A plurality of radial ports or openings 36 are
18 formed through delivery member 16 proximally of circumferential edge 34. As
19 shown in Fig. 3, four radial ports 36 are formed through the wall of delivery
20 member 16 at spaced locations about a central longitudinal axis 38 of delivery
21 member 16. The ports 36 are shown as being equally spaced about the central
22 longitudinal axis 38 at 90 degree spaced locations about the central longitudinal
23 axis 38. It should be appreciated, however, that the ports 36 can be equally

1 spaced or variably spaced about the central longitudinal axis. The ports 36 are
2 shown as having a circular perimetrical configuration, but the ports can have
3 other perimetrical configurations including oval, elliptical and various
4 longitudinally elongated perimetrical configurations. Each port 36 has a
5 longitudinal dimension in a direction parallel to the central longitudinal axis 38. In
6 the case of ports 36, the longitudinal dimension corresponds to the diameter of
7 the ports. Each port 36 begins a distance D proximally of the proximal most edge
8 segment or point of circumferential edge 34 as shown in Fig. 2. Where the
9 circumferential edge is disposed in its entirety in a plane perpendicular to the
10 central longitudinal axis 38, the proximal most edge segment or point will be
11 disposed in the plane perpendicular to the central longitudinal axis 38 as
12 described below for Figs. 6 and 7. Distance D may be in the range of 0.020 inch
13 to 0.275 inch. For delivery member 16 having ports 36 that are 0.063 inch in
14 diameter, the longitudinal dimension for ports 36 is also 0.063 inch and a
15 preferred range for distance D is 0.0505 inch to 0.0805 inch. Fig. 2 illustrates a
16 removable tubular sheath 40 that may be disposed over the delivery member 16
17 prior to use.

18 In a preferred embodiment for bone graft needle 12, the needle is a 4 inch
19 needle with delivery member 16 made of 304 stainless steel or other rigid
20 biocompatible material and having a J-type cannulated distal end or tip; the
21 delivery member is 0.185 inch in diameter; the radial ports 36 are 0.063 inch in
22 diameter with centers at 90° (+ or - 2.0°) spaced locations about the central
23 longitudinal axis; and the centers of ports 36 are located 0.082 inch (+ 0.030

1 inch, - 0.000 inch) proximally of the proximal most edge segment or point of
2 circumferential edge 34. The needle 12 may be a JAMSHIDI - type needle with a
3 luer-lock coupling or connector.

4 The open distal end 20 defines an axial or longitudinal port for delivery
5 member 16 from which a bone graft material is discharged from delivery member
6 16 in an axial or longitudinal direction. The radial ports 36 permit bone graft
7 material to be discharged from delivery member 16 in a direction radial to the
8 central longitudinal axis 38 so that bone graft material is discharged radially
9 simultaneously with the axial discharge.

10 In a method according to the present invention, the distal end 20 of
11 delivery member 16 is introduced at or near a bone defect area in a patient's
12 body via a minimally invasive portal providing access to the bone defect area
13 from externally of the patient's body. As discussed above, the bone graft needle
14 12 may be assembled with a penetrating member to form an instrument
15 assembly that may be used to form the portal. Visualization of the bone defect
16 area may be accomplished using a remote viewing device, such as a fluoroscope
17 or x-ray device, as conventionally utilized in minimally invasive procedures. Fig. 2
18 illustrates a bone segment 42 having a bone defect area 44 to be supplied with a
19 bone graft material delivered via the bone graft needle 12. The bone defect area
20 44 may include metaphyseal compression fractures, bone voids, discontinuities,
21 cavities, recesses, non-unions or the like. The bone graft material to be delivered
22 to the bone defect area may be any synthetic or tissue-based material that
23 promotes bone growth and may be provided in paste form. Representative bone

1 graft materials include calcium sulfate, as represented by the OSTEOSSET® bone
2 graft substitute of Wright Medical Technology, Inc., Allomatrix® and MIIG™ 115
3 of Wright Medical Technology, Inc., and demineralized bone matrix. The bone
4 graft material is supplied to the bone graft needle 12 via a conventional syringe
5 coupled with the coupling 24. With the handle 18 disposed externally of the
6 patient's body, the syringe containing the bone graft material is coupled with
7 coupling 24. The distal end 20 of delivery member 16 is positioned at or adjacent
8 the bone defect area 44 and, depending on the size of the bone defect area, the
9 distal end 20 may be positioned within the bone defect area. With the distal end
10 20 properly positioned, a plunger of the syringe is depressed to fill the passage
11 22 with the bone graft material. Depressing the plunger of the syringe
12 pressurizes the bone graft material in passage 22 causing the bone graft material
13 to be simultaneously discharged axially through distal end 20 and radially
14 through the ports 36 to fill the bone defect area 44. In the case of delivery
15 member 16, the bone graft material is discharged simultaneously in five
16 directions, i.e. in a first direction axially or longitudinally through distal end 20 and
17 in second, third, fourth and fifth radial directions through ports 36, respectively. In
18 the event that the distal end 20 is in abutment with bone or other anatomical
19 tissue, plugging or clogging of the delivery member 16 is avoided since discharge
20 of the bone graft material continues through ports 36. In addition, back pressure
21 is reduced for easier injection of the bone graft material since resistance to
22 injection is reduced due to the multi-directional discharge provided by opening 20
23 and ports 36. The arrangement of ports 36 along the circumference of delivery

1 member 16 permits radial discharge and distribution of the bone graft material
2 and allows the bone defect area to be filled radially as well as from the distal end
3 20 of the delivery member. The distribution of ports 36 along the circumference
4 of the delivery member allows the bone defect area to be filled in a range of 360
5 degrees around the delivery member. Also, the circumferential distribution of the
6 ports 36 provides a more even and more balanced distribution of bone graft
7 material to the bone defect area. Once the bone defect area 44 has been
8 sufficiently supplied or filled with the bone graft material, the needle 12 is
9 removed from the patient's body through the portal. The bone graft material
10 remains in the patient's body to promote bone growth or regeneration.

11 Fig. 4 illustrates an alternative instrument assembly 110 comprising a
12 bone graft needle 112 and a penetrating member 114. The instrument assembly
13 110 is similar to instrument assembly 10 except that the bone graft needle 112
14 and the penetrating member 114 are shorter in length than the bone graft needle
15 12 and penetrating member 14. Accordingly, it should be appreciated that the
16 bone graft needle, as well as the penetrating member, can be provided in
17 different lengths depending on the length needed to access the bone defect area.
18 The bone graft needle 112 also differs from the bone graft needle 12 in that the
19 delivery member 116 is of smaller external diameter than the delivery member
20 16. It should be appreciated, therefore, that the delivery members of the bone
21 graft needles can be provided in various diametric sizes. Of course, the shafts of
22 the penetrating members can also be provided in various diametric sizes
23 depending on the anatomical tissue to be penetrated. The radial ports 136 for

1 delivery member 116 differ from the ports 36 in that the ports 136 are smaller in
2 diameter.

3 In a preferred embodiment for bone graft needle 112, the external
4 diameter of delivery member 116 is 0.115 inch; the ports 136 have a diameter of
5 0.047 inch with centers at 90° (+ or - 2.0°) spaced locations about the central
6 longitudinal axis 138; distance D may be in the range of 0.020 inch to 0.275 inch
7 and is preferably in the range of 0.082 inch to 0.112 inch; the needle 112 is a 6
8 cm needle with delivery member 116 made of 304 stainless steel or other rigid
9 biocompatible material and having a J-type cannulated distal end or tip; and the
10 centers of ports 136 are located 0.082 (+ 0.030 inch, - 0.000 inch) proximally of
11 the proximal most edge segment or point of circumferential edge 134. The
12 needle 112 may be a JAMSHIDI-type needle with a luer-lock coupling or
13 connector.

14 Fig. 6 is illustrative of a bone graft needle 212 in which the delivery
15 member 216 has a distal end 220 with a circumferential edge 234 disposed in a
16 plane perpendicular to the central longitudinal axis 238. Distance D for delivery
17 member 216 is defined from the plane of edge 234 to where the ports 236 begin
18 proximally of edge 234.

19 The bone graft needle 312 illustrated in Fig. 7 is representative of a
20 delivery member 316 having radial ports 336 that are not circular in perimetrical
21 configuration. The radial ports 336 are formed as elongate slots in delivery
22 member 316, and the slots begin a distance D proximally of the circumferential

1 edge 334, which is disposed in a plane perpendicular to central longitudinal axis
2 338.

3 Inasmuch as the present invention is subject to many variations,
4 modifications and changes in detail, it is intended that all subject matter
5 discussed above or shown in the accompanying drawings be interpreted as
6 illustrative only and not be taken in a limiting sense.